UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/533,659	05/05/2005	Masahiro Nishimura	270257US0XPCT	1362

22850 7590 03/25/2009

OBLON, SPIVAK, MCCLELLAND MAIER & NEUSTADT, P.C.
1940 DUKE STREET
ALEXANDRIA, VA 22314

EXAMINER	
KAROL, JODY LYNN	

ART UNIT	PAPER NUMBER
1617	

NOTIFICATION DATE	DELIVERY MODE
03/25/2009	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

patentdocket@oblon.com
oblonpat@oblon.com
jgardner@oblon.com

Office Action Summary	Application No.	Applicant(s)	
	10/533,659	NISHIMURA ET AL.	
	Examiner	Art Unit	
	Jody L. Karol	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *29 December 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-18* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-18* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 12/29/2008 has been entered.

Claims 1-18 are currently pending and examined on the merits herein.

Response to Amendment

2. The declaration under 37 CFR 1.132 filed 12/29/2008 is insufficient to overcome the rejection of claims 1-18 based upon obviousness under 35 U.S.C. 103(a) in view of Hara et al. (EP 1 224 937 A1) as set forth in the last Office action because: the facts presented pertain to a showing that is not commensurate in scope with the claims. See Response to Arguments *infra* for a detailed response.

Response to Arguments

Applicant's arguments filed 12/29/2008 have been fully considered but they are not persuasive.

Applicant alleges that the differences in stirring aptitude and extensibility are meaningful difference in ointment preparations and thus constitute unexpected results because a marked improvement over the prior art has been demonstrated, as to be classified as a difference in kind rather than one of degree. In response, it is respectfully submitted that the results submitted in the 11/19/2008 between the Product of the Invention and the Supplemental Product 1 at room temperature differ only in that the product of the invention is very easily stirred/extensible and the Supplemental Product 1 is easily stirred/extensible. This does not constitute a patentable difference. While it is agreed that a difference in kind does exist for ointment preparations that are very easily or easily stirred/extensible and ointment preparations that are difficult or very difficult to stir/extend, it is not agreed upon that a difference in kind exists for ointment preparations that are very easily and or easily stirred/extensible. In the first case, the comparison is between ointment preparations that are useable and ointment preparations that are unusable. In the second case, the comparison is between two ointment preparations that are usable, with one having a degree of improvement over the other. This difference is not a marked improvement or unexpected results, but a difference in degree in usability.

Further, it is applicant's burden to demonstrate unexpected results over the prior art. See MPEP 716.02, also 716.02 (a) - (g). Furthermore, the unexpected results should be demonstrated with evidence that the differences in results are in fact unexpected and unobvious and of both statistical and practical significance. *Ex parte Gelles*, 22 USPQ2d 1318, 1319 (Bd. Pat. App. & Inter. 1992). Moreover, evidence as to

any unexpected benefits must be "clear and convincing" *In re Lohr*, 137 USPQ 548 (CCPA 1963), and be of a scope reasonably commensurate with the scope of the subject matter claimed, *In re Linder*, 173 USPQ 356 (CCPA 1972).

In the instant case, the evidence present is not of a scope reasonably commensurate with the scope of the subject matter claimed. The claims are directed to formulations comprising 50 to 90% by weight saccharide and 0.5 to 10% povidone-iodine, and 0.1 to 20% by weight water, while the formulations presented Table of the instant specification (see page 10) and in Table 1 of the declaration submitted 11/19/2008 all have 70% by weight saccharide, 35 by eight povidone-iodine, and approximately 9.52% by weight water. Only the amount of phospholipid is varied, which does not provide sufficient evidence that the remaining composition formulations possible under the claim scope would exhibit the same are similar results as those presented in the instant specification or the 11/19/2008 declaration. Therefore, no clear and convincing unexpected benefit is seen to be present herein.

Thus, for these reasons, Applicant's arguments are found unpersuasive. Said rejection is maintained and the instant claims are still considered properly rejected under 35 USC 103(a).

MAINTAINED REJECTIONS

3. The following rejections have been maintained from the previous Office Action dated 3/25/2008:

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

5. Claims 1-18 rejected under 35 U.S.C. 103(a) as being unpatentable over Hara et al. (EP 1 224 937 A1).

The instant claims are directed to compositions for repairing injured skin comprising 50 to 90% by weight of saccharide, 0.5 to 10% by weight of povidone-iodine, 0.1 to 20% by weight of water, and 0.3 to 5% by weight of phospholipid.

Hara et al. teaches formulations for the treatment of bedsores, skin ulcers, or wounds, comprising 0.5 to 20% by weight of gelatin, 50 to 90%, preferably 60 to 80% by weight of sugar, and 0.5 to 10% by weight of an iodophor such as povidone-iodine, at a pH of 4-6 (see abstract and page 3, lines 38-39, and 45-50). In the examples, Hara et al. teaches water is present in 0-21% by weight (see page 5, Example 2, and page 6, Example 4). Hara et al. further teaches that additional components such as hydrogenated lecithin, a hydrogenated soybean phospholipid, may be present in up to 40% by weight (see page 3, line 55 to page 4, line 8).

In regards to the instant claims 2 and 7, Hara et al. teaches that sucrose, a soft white sugar, is preferable (see page 3, lines 42-44).

In regards to the instant claims 6, and 8-11, Hara et al. teaches in the examples compositions comprising the components within the claimed ranges. For instance, Example 2 comprises 70% by weight saccharide, 3% by weight povidone-iodine, and 1.5, 2.5, 3.5, 5, or 10% by weight water (see page 5, Example 2).

In regards to claims 13-16, Hara et al. teaches that the formulation can be combined with additional components such as base agents, thickeners, emulsifiers, stabilizers, and solvents that are used in pharmaceuticals. Among others, polyethylene glycol, alginic acid and salts thereof, polyoxyethylene alkyl ethers, polyoxyethylene hydrogenated castor oils, polyabsorbate, and sodium iodide are mentioned as the

additional components (see page 3, lines 55 to page 4, line 7). Furthermore, gelatin, a thickener, is present in all of the compositions taught by Hara et al.

Hara et al. does not explicitly teach a composition where lecithin is present within the claimed range. However, it would have been obvious to one of ordinary skill in the art at the time of the invention to utilize the teachings of Hara et al. to formulate the claimed compositions with the lecithin and to optimize the amount of lecithin present. In this case, where the claimed ranges "overlap or lie inside ranges disclosed by the prior art" a prima facie case of obviousness exists. *In re Wertheim*, 541 F.2d 257, 191 UPSQ 90 (CCPA 1976). Furthermore, while the references do not explicitly teach the claimed range of lecithin, it is the Examiner's opinion that the determination of optimal or workable range of lecithin by routine experimentation is obvious absent showing of criticality of the claimed range. One having ordinary skill in the art would have been motivated to do this to obtain the desired emulsifying effects of lecithin.

Therefore, the invention as a whole would have been *prima facie* obvious to one skilled in the art at the time it was made.

Conclusion

No claims are allowed.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jody L. Karol whose telephone number is (571)270-3283. The examiner can normally be reached on 8:30 am - 5:00 pm Mon-Fri EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on (571) 272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

/Jody L. Karol/

Examiner, Art Unit 1617

/JENNIFER M KIM/
Primary Examiner, Art Unit 1617